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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---------------------|------|-------------|----------------------|---------------------|------------------|--|
| 10/031,841 | | 01/22/2002 | Douglas Clark Fraser | KNI-004CPUS | 5745 | |
| 959 | 7590 | 09/19/2005 | | EXAMINER | | |
| | | FIELD, LLP. | WANG, CHANG YU | | | |
| 28 STATE BOSTON, | | 19 | | ART UNIT | PAPER NUMBER | |
| , | | | | 1649 | | |

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------|--|--|--|--|
| | Application No. | Applicant(s) | | | | | |
| | 10/031,841 | FRASER ET AL. | • | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Chang-Yu Wang | 1649 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this c D (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>20 A</u> | oril 2005. | • | | | | | |
| | action is non-final. | | | | | | |
| , | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 53 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1,6,8-10,13,15,20 and 22</u> is/are pendi | ng in the application. | • | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8)⊠ Claim(s) <u>1, 6, 8-10, 13, 15, 20,and 22</u> are subje | ect to restriction and/or election re | equirement. | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | • | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | · | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| • | | | | | | | |
| Attachment(s) | _ | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Do | | O-152) | | | | |
| Paper No(s)/Mail Date | 6) Other: | | | | | | |

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Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

- 2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
 - Groups I-V, claims 1, 6, and 8, drawn to the first to fifth technical features polypeptides derivable from human NESP55 as taught by prior art reference and are delineated in the further restriction requirement.
 - Group VI, claims 9, 10, and 13, drawn to the sixth technical feature, a recombinant polynucleotide and a method of making polypeptide.
 - Group VII, claim 15, drawn to the seventh technical feature, an antibody toward the polypeptide derived from human NESP55.
 - Group VIII, claim 20, drawn to the eighth technical feature, a method of treating or preventing obesity in a patient
 - Group IX, claim 22, drawn to the ninth technical feature, a method of identifying a polypeptide that is capable of interacting with a polypeptide derived from human NESP55
 - Group X, claim 22, drawn to the tenth technical feature, a method of isolating a polypeptide that is capable of interacting with a polypeptide derived from human NESP55.

3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The 1st claimed invention is drawn to the polypeptide of SEQ ID NO: 2 which does not recite functional limitation for the recited molecule. Therefore, claim 1 does not recite a special technical feature, defined by the PCT rules as a feature that defines a contribution over the prior art. As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Ischia et al. "Molecular cloning and characterization of NESP55, a novel chromogranin-like precursor of a peptide with 5-HT1B receptor antagonist activity. J Biol Chem. 1997 Apr 25;272(17):11657-62

Ischia et al. teach NESP55 meeting the limitation of claim 1 at Figure2.

Therefore, claim 1 is anticipated by Ischeia et al..

Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions." Thus, Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single inventive concept and so lack unity of invention.

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4. Furthermore, in addition to the election of one of the above X groups, further restriction is required under PCT Rule 13.1 to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:

A. If one of Groups I-V above is elected then a single designated amino acid composition (SEQ ID NO:) selected from SEQ ID NOs 2, 11, 12, 5, or 6 is required to be designated to which the search will be limited.

- B. If Group VI is elected, a single designated nucleic acid sequence encoded for polypeptide selected from is required to elect.
- C. If Groups VII or VIII is elected, a single designated antibody is required to elect. In addition, Applicant is required to identify the corresponding amino acid sequence.

Polypeptides, polynucleotides and antibodies are directed to different products, thus, restriction is deemed to be proper. The products indicated as group A-C constitute patentably distinct inventions for the following reasons. Each of the polypeptides, nucleotides and antibodies has a unique structural feature, capable use, function and effects. In addition, the polypeptides derivatives of NESP55 have their unique functions and are linked by a special technical feature.

Therefore, they have no common technical feature. In addition, it requires a unique search of the prior art for each molecule. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

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- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-X and a single molecular embodiment (sequence) as set forth above to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-X nor the single molecular embodiment (sequence) are species election requirements; rather each of I-X and the elected sequence are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, PhD. whose telephone

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number is 571-272-4521. The examiner can normally be reached on Monday

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through Friday 8:00am to 5:00pm.

9. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867.

The fax phone number for the organization where this application or proceeding

is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).

CYW

September 8, 2005

SUPERVISORY PATENT EXAMINER